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EXHIBIT A

1985 WL 83812 (F.R.)

(Cite as: 50 FR 2172)

PROPOSED RULES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 333

[Docket No. 81N-0114]

Topical Acne Drug Products for Over-the-Counter Human Use; Tentative Final
Monograph

Tuesday, January 15, 1985

*2172 AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) topical acne drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by May 15, 1985. New data by January 15, 1986. Comments on the new data by March 17, 1986. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and classifying OTC drugs (21 CFR 330.10).

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

Supplementary information: In the Federal Register of March 23, 1982 (47 FR 12430) FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical acne drug products, together with the recommendations of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 21, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by July 21, 1982.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information. In response to the advance notice of proposed rulemaking, eight drug manufacturers, one drug manufacturer association, one consulting firm, three physicians, and one consumer submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

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List of Subjects in 21 CFR Part 333

OTC drugs; Topical acne drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under 21 CFR 5.11, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 333 (which was proposed to be added in the Federal Register of January 6, 1978 (42 FR 1210)) by revising proposed Subpart D, to read as follows:

PART 333--TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart D--Topical Acne Drug Products

333.301 Scope.

333.303 Definitions.

333.310 Acne active ingredients.

333.320 Permitted combinations of active ingredients.

333.350 Labeling of acne drug products.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart D--Topical Acne Drug Products

§ 333.301 Scope.

(a) An over-the-counter acne drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 333.303 Definitions.

As used in this subpart:

(a) Acne. An inflammatory skin disease involving the oil glands and hair follicles of the skin.

(b) Acne drug product. A drug product used to reduce the number of acne lesions.

(c) Blackhead. An acne lesion characterized by a black tip.

(d) Pimple. A small, prominent, inflamed elevation of the skin.

§ 333.310 Acne active ingredients.

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The active ingredient of the product consists of any of the following when labeled according to § 333.350.

- (a) Benzoyl peroxide 2.5 to 10 percent.
- (b) Resorcinol 2 percent when combined in accordance with § 333.320(a).
- (c) Resorcinol monoacetate 3 percent when combined in accordance with § 333.320(b)
- (d) Salicylic acid 0.5 to 2 percent.
- (e) Sulfur 3 to 10 percent.
- (f) Sulfur 3 to 8 percent when combined in accordance with § 333.320.

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(b) when combined with sulfur identified in § 333.310(f) provided the product is labeled according to § 333.350.

(b) Resorcinol monoacetate identified in § 333.310(c) when combined with sulfur identified in § 333.310(f) provided the product is labeled according to § 333.350.

§ 333.350 Labeling of acne drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "acne medication."

(b) Indications. The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the following:

(1) "For the" (select one of the following: "treatment" or "management") "of acne."

(2) Other allowable indications. In addition to the required indication identified in paragraph (b)(1) of this section, the labeling of the product may contain additional indication statements that are limited to one or more of the following:

(i) (Select one of the following: "Dries," "Dries up," "Dries and clears," "Clears," "Clears up," "Clears up most," "Helps clear," "Helps clear up," "Reduces the number of," or "Reduces the severity of") (select one or more of the following: "blackheads," "acne pimples," or "acne blemishes") which may be followed by "and allows skin to heal."

(ii) "Penetrates pores to" (select one of the following: "eliminate most," "control," "clear most," or "reduce the number of") (select one or both of the following: "blackheads" or "acne pimples").

(iii) "Helps keep skin clear and new acne pimples."

(iv) "Helps prevent new" (select one or more of the following: "blackheads," "acne pimples," or "acne blemishes") which may be followed by "from forming."

(v) "Helps prevent the development of new acne pimples."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) For products containing any ingredient identified in § 333.310. (i) "For external use

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STATUS: Married.

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QUALIFICATIONS: BSc (Hons) Physiol. London 1956.
MBBS (Hons) London 1959.
DTM&H England 1961.
MRCP London 1964.
FRCP London 1977.
MRCPATH 1980.
FRCPATH 1985.

PRESENT POSITION:

Emeritus Professor
University of Wales College of Medicine
Heath Park
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Medical Director, Cutest Systems Ltd
214 Whitchurch Road
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Cardiff CF14 3ND

Clinical Professor
Department of Dermatology
University of Miami School of Medicine
Miami, Fl
USA

EDUCATION:

St Marylebone Grammar School 1946-1953
Guy's Hospital Medical School 1953-1958
(Open Scholarship and State Scholarship 1953)

October - December 1958 House Physician, Guy's Hospital, London.

February - September 1959 House Surgeon, Guy's Surgical Unit at New Cross General Hospital.

September 1959 - March 1960 House Physician, Cuckfield General Hospital.

(b) Army Service

March 1960 National Service Medical Officer.

April 1960 Short Service Commission.

December 1960 Passed Junior Officer Course, appointed Trainee Specialist in Dermatology.

March 1961 Attended Course in Tropical Medicine, awarded DTM & H.

March 1961 - September 1963 Appointed to Medical Division, Queen Alexander Military Hospital.

September 1963 - June 1965 Appointed Specialist in Dermatology, British Military Hospital, Münster, W Germany.

(c) Experience subsequent to the Army

June 1965 - March 1967 Registrar in Dermatology, St George's Hospital, London.

March 1967-
December 1968 Senior Registrar and Tutor, St John's Hospital for Diseases of the Skin, London.

December 1968-
December 1969 Senior Resident in Dermatology, University of Miami, USA.

December 1969-
July 1971 Senior Registrar and Tutor, St John's Hospital for Diseases of the Skin, London.

July 1971 Appointed as Research Fellow (Senior Lecturer), Institute of Dermatology, and Honorary Consultant Dermatologist at St John's Hospital for Diseases of the Skin, London.

October 1972 Appointed Consultant Dermatologist at St John's Hospital for Diseases of the Skin, London.

October 1973 Appointed Senior Lecturer in Dermatology, Department of Medicine, Welsh National School of Medicine, Cardiff (now University of Wales College of Medicine) and Honorary

October - November 1976 Visiting Professor at John Hopkins Hospital, Baltimore, USA.

March 1977 Appointed Reader in Dermatology, University of Wales College of Medicine, Cardiff.

December 1980 - 1998 Chair in Dermatology in the University of Wales College Of Medicine, Cardiff.

OTHER APPOINTMENTS AND AWARDS

October 1980 Awarded MRCPPath for published work.

April 1984 Dowling Oration Lecturer.

April 1985 Awarded FRCPPath.

May 1985 Parkes Weber Lecturer.

August 1985 Life President of The International Society of Bioengineering and the Skin.

October 1985 Literature Award (1984) of the Society of Cosmetic Chemists.

March 1987 Appointed Regional Consultant to the Department of Health & Social Security for War Pensions Cases in Wales.

November 1990 Appointed external examiner to the Royal College of Pathologists Diploma in Dermatopathology.

October 1992 - 1996 Appointed external examiner to the Queen's University of Belfast School of Pharmacy.

March 1993 Society Of Cosmetic Scientists Medal Lecturer.

February 1994 - 1997 Appointed Regional Representative for Wales 1994-1997, Executive Committee, British Association of Dermatologists .

June 1994 Elected President of The British Cosmetic Dermatology Group.

July 1994 - 1996 Chairman, Welsh Dermatological Sub-committee of the Welsh Medical Committee.

June 1995 Appointed Clinical Professor, Department of Dermatology and Cutaneous Surgery, University of Miami School of Medicine, USA.

June 1996 - 1998 Appointed Speciality Adviser to the Royal College of Physicians.

I am a member of the Medically Qualified Panel of Appeals
Tribunals (Part Time) 2003-

i. I have organised or helped organise the following symposia and meetings:

A symposium on Mechanisms of Action of Topical Corticosteroids held in London in November 1974.

A symposium (sponsored by the European Society for Dermatological Research) on Dermatitis Herpetiformis, held in Lund, Sweden, with Professor Hans Rorsman, in January 1976.

A symposium on Methods for Measurement of Physical Properties of the Skin (with Professor Harvey Blank) held in Miami in 1976.

A symposium (European Society for Dermatological Research) on The Ichthyoses, held in Cardiff in January 1977.

A symposium entitled "The Epidermis in Disease" (with Professor E Christopher's) held in Cardiff in April 1979.

A symposium entitled "Bioengineering and the Skin" (with Professor P Payne) held in Cardiff in July 1979, followed by further meetings in Philadelphia (1981), Besançon (1983), San Francisco (1985), Liege (1986), Milwaukee (1988), and Stresa, Italy in 1990.

Investigative Techniques in Dermatology courses in alternate years since 1975, and a course entitled Histopathology of the Skin, with Dr Arthur Knight, in alternate years since 1978.

A symposium entitled 'The Stratum Corneum' (with Professor Gerd Plewig) held in Cardiff in October 1981.

A symposium entitled "Skin Models" (with Professor G Plewig) held in Cardiff in March 1984.

A three-day course and presentation of new data entitled "Physical Nature of the Skin", in November 1985.

A symposium entitled "Acne and Related Disorders" (with Professor G. Plewig) held in Cardiff in March 1988.

A symposium entitled "The Environmental Threat to the Skin" (with Professor G Plewig) held in Cardiff in April 1991.

A symposium entitled "Skin Therapy Forum — A Future Look" (with Dr W J Cunliffe) held in Cardiff in October 1992.

A symposium entitled "Skin Therapy Forum II - A Future Look" (with Dr W J Cunliffe) held in Cardiff in October 1994.

A symposium entitled '20th Anniversary of the International Society of Bioengineering and the Skin' held in Miami in February 1996.

A symposium entitled "Skin Therapy Forum III" (with Professor W J Cunliffe) held in Cardiff in October 1996.

A symposium entitled "Skin Therapy Forum IV" (with Professor W J Cunliffe) held in Cardiff in October 1998.

A symposium entitled "Skin Therapy Forum V" (with Professor W J Cunliffe) held in Leeds in September 2000.

A symposium entitled "Stratum Corneum III held in Basel 2003.

2. I was co-editor of the Journal of Dermatological Treatment from 1989 - 1997. I am a reviewer for the Journal of Investigative Dermatology, a member of the editorial boards of Epithelial Cell Biology, the European Journal of Pediatric Dermatology, and the Journal of Geriatric Dermatology, and a member of the International Advisory Board of Chronica Dermatologica. I was an assistant editor for the British Journal of Dermatology (1973 - 1985) and was managing editor of the Archives for Dermatological Research. I am on the editorial board of American Journal of Clinical Dermatology.

Fellow of the Royal College of Physicians.
Fellow of the Royal College of Pathologists.
Member of the St. John's Hospital Dermatological Society.
Member of the British Association of Dermatologists.
Member of the Royal Society of Medicine.
Member of the Society of Cosmetic Chemists.
Member of the European Society for Clinical Investigation.
Member of "The Skin Club" (Secretary 1975-1979).
Member of European Society for Dermatological Research (President) 1978-1979).
Member of the Association of Physicians of Great Britain and Ireland.
Corresponding member of the Swedish Dermatological Society.
Corresponding member of the Israeli Dermatological Society
Corresponding member of the Polish Association of Dermatology.
Corresponding member of the Pacific Dermatologic Association.
Corresponding member of the Italian Society of Dermatology.
Corresponding member of the German Dermatological Society (Deutsche Dermatologische Gesellschaft).
Life President of the International Society for Bioengineering and the Skin.
Member of the American Academy of Dermatology.
Member of the International Society of Dermatopathology.
Member of the British Society for Investigative Dermatology.
Member of the British Dermatological Surgery Group.
Member of the Biological Engineering Society.
Member of Advisory Board, International Society of Cosmetic Dermatology.
Member of the Executive Board of the Skin Pharmacology Society.
Member of the Chilean Dermatological Society.
Member of the Korean Dermatological Society.
Member of the Distinction Award Committee, Royal College of Physicians.
Member of the Editorial Advisory Board of Reviews in Contemporary Pharmacotherapy.
Member of the Editorial Advisory Board of the Skin Research & Technology Journal.
Member of the Editorial Board of Current Medical Research & Opinion Journal.
Member of the Editorial Board of Dermatology in Clinical Practice.
Member of the Editorial Board of the American Journal of Clinical Dermatology.
Member of the London Expert Witness Institute.
Member of the Wales Medico-Legal Society.

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